

**MINUTES OF THE
IDAHO STATE BOARD OF PHARMACY
April 23, 2010**

Hampton Inn
Pocatello, Idaho

This meeting of the Board is held to conduct regular Board business.

Chairman Nicole Chopski, Pharm D, called the meeting to order at 8:00 a.m. In attendance were Board members Berk Fraser, R.Ph.; Holly Henggeler, Pharm D; and Rich de Blaquiere, Pharm D; and Mark Johnston, R.Ph, executive director; Jenifer Marcus, DAG; Jan Atkinson, Senior Compliance Officer; Fred Collings, Chief Investigator, Mike Brown, Compliance Officer and Ellen Mitchell. Although Ms. Gurnsey is not present at this meeting, having four members present creates a quorum.

Dr. Henggeler motioned to approve the minutes of the January 28, 2010 meeting with punctuation corrections. Mr. Fraser seconded, motion carried unanimously.

As follow-up to outstanding issues listed in the 1/28/10 minutes, Mr. Johnston gave a brief overview of the final portion of the 2010 Legislative Session, including the naturopath bill that never went to hearing, thus giving their association no reason to return to the Board of Pharmacy this year, as they had initially requested. Mr. Johnston contacted the Board of Medicine (BOM) regarding practitioner deliver of legend drugs to ultimate users. BOM invited Mr. Johnston to attend their next meeting to address the issue. Since their next meeting falls while our Board is in Coeur d' Alene for its next open, public meeting, Mr. Johnston is preparing an informational letter comparing physician delivery of legend drugs versus pharmacy dispensing for the BOM agenda. Dr. Henggeler asked for Glenn Luke to present to BOM. Dr. Chopski asked for updated status of the cease and desist letter from the attorney general's office regarding hcg. Mr. Johnston indicated they are still gathering information to create the letter.

Lynette Berggren and Mr. Johnston presented an update on the rules rewrite project. Mr. Johnston indicated there were few changes to chapter 1 since the last review, and the Board was unopposed to said changes. Dr. Chopski commended Ms. Berggren on proposed language related to required policy and procedure manuals in certain pharmacy practice settings. Ms. Atkinson indicated that veterinary drug technicians must have an employer relationship with a veterinary drug outlet as their registration does not stand on their own. If the new proposed rules are ready, the Board can submit in August 2010, although Mr. Johnston believes it would be better to wait and gather more public comment.

Chapter 2 currently contains 116 definitions, although some will become rules due to their substantive nature. Much work remains on definition language.

Proposed rule #13: Uniform Controlled Substance (CS) Act Enforcement: The Board decides to retain current rule #470, relating to practitioners using the appropriate forms when writing CS prescriptions. The rule is quite lengthy and is the product of negotiated rule making.

Proposed rule #14: Waivers or Variances: Mr. Johnston presented the newly expanded waiver language, as per AG direction and asked the Board if they would consider delegating authority to the Board staff regarding certain waivers and variances versus having the applicant appear before the Board. Some other Boards have allowed certain waivers to be handled by Board staff, such as a waiver of the restroom requirement in a pharmacy during remodeling. Mr. Johnston is also concerned with proposed language that would require a hearing to revoke an approved waiver. Ms. Marcus indicated that a provision detailing the waiver revocation process needs to be stated in the letter granting the waiver. The Board staff is to develop a list of waiver categories for delegation for future approval. Each waiver approved by the Board staff is to be e-mailed to the Board. The Board eliminates the requirement of a hearing to revoke a waiver.

Proposed rule #015 Prescription Monitoring Program: There have been several deletions to this section due to overlap with statute. All references to password sharing have been eliminated in an effort to give practitioners more leeway in accessing the database. Mr. Collings clarified when passwords are used, the Board is able to track each login to a specific IP address. Ultimately the practitioner is responsible for the information obtained using their password, as per the Uniform Controlled Substance Act. Misuse of the information is a misdemeanor. The Board approved as written.

Proposed rule #020 Advertising – Several existing Board advertising rules are also overlapping and regulated by other agencies, thus these existing rules are proposed to be struck. Mr. Johnston indicated two of the advertisement rules remain as per previous Board direction, but that a third, newly proposed rule, prohibiting pharmacies that are not licensed in Idaho from advertising in Idaho, was contested by Dr. de Blaquiére, who addressed concerns from border pharmacies. Mr. Johnston asks to remove this proposed language on the advice of counsel; permission granted.

Proposed rule #030: Minimum Prescription Order Requirements: after discussion it is agreed: “dosage form” to be moved to the CS requirement only, to be consistent with DEA CFR. The Board removes the CII hard copy signature requirement. The Board is concerned with existing language that requires a written signature and if current language allows e-signature. Board staff is directed to research.

Proposed Rule #50: CS: Board approves of language rearranging the positive ID rule, but not changing the intent of current rule #464. The Board approves of new language concerning prescribing for relatives and oneself and reiteration of the CFR on multiple CII prescriptions, with minor changes, and eliminates current rule 444.04.b.

Proposed rule # 51: CS: Mr. Johnston indicates that proposed rule 51.01c allows pharmacist to add information concerning the patient being enrolled in a hospice program to faxed Schedule II prescriptions. The Board approves of language, including summary language of federal language concerning multiple CII prescriptions.

Proposed rule #52: CS Non Prescription Dispensing: The Board eliminates the Official Idaho Register and replaces with a “bound book”.

Proposed rule #61: Drug Product Selection: The Board removes much current language and replaces it with a reference to the Orange Book. The Board questions the ability of pharmacies’ ability to collect dispensed medication’s manufacturer or NDC# in the electronic record. Board staff directed to research.

Proposed rule #65: Compounding: The Board staff directed to research USP/NF monograph parameters verses FDA approved status. The Board approves proposed language, including referencing but not requiring USP 797, but eliminates proposed language concerning advertisement. The Board directs Mr. Johnston to create a compounding rules review committee.

Proposed rule #70: Prescription Refill: The Board approves extension of 2010 approved changes to current rule #184, which, in certain situations, allow a pharmacist to dispense the full quantity of a prescription, when a practitioner has authorized a lesser quantity with adequate refills. Current rule #184 restricts said dispensing to a 3 month supply.

Proposed rule #75: Electronic record keeping: The goal of this proposed language is to require pharmacy computer systems and to establish minimum requirements therein, thus eliminating many hard copy report requirements. Much discussion and concern ensues regarding mandatory record keeping and audit trails in both the retail and institutional setting. The Board directs Mr. Johnston to create an institutional rules review committee, as ISHP has failed to return to the Board with results from a similar committee. Proposed rule #75 not approved as written.

Proposed rule #80: Prescription labeling. After much discussion, proposed language is approved, including new expiration date language, and the current warning language is removed. The Board has concerns of drug order labeling Vs prescription order labeling. The Board staff is directed to research said concerns.

Proposed rule #90: Prescription Transfer. Requirement to document all previous fill locations moved to requirements for CS only. Language requiring electronic record keeping and eliminating paper documentation is approved. Discussion concerning “common electronic File” Vs “real-time on-line” language ends with the Board directing the Board staff to research additionally.

During the Public Comment period Julianne Ramirez, a student pharmacist from ISU, requested a change to Rule 152 as it relates to reference library, adding Lexicom as one of the approved references. Ms. Ramirez also shared her research on several databases and showing they were all equal. Lexicom has already been added to the proposed language. The Board thanks Ms Ramirez.

John Southworth of Southworth Associates addressed the Board with the basic parameters and cost of the PRN program and an update of the enrollees. A discussion of the parameters continued with the Board agreeing impairment is impairment whether by drugs or alcohol. The Board defines “volunteering” as contacting Southworth Associates and scheduling an evaluation as part of the PRN program within 72 hours of notifying the Board of the need for treatment. “Volunteers” are most likely not facing suspension, while “non-volunteers”, including those who have been arrested, terminated by their employers, and those who have not initiated contact with the Board on their own, are most likely facing a one year suspension. The Board thanks Mr. Southworth and approves of the PRN program’s current parameters with the clarification listed herein.

Ben Gage, RPh, addressed the Board requesting early termination of his probation. Dr. Henggeler motioned to accept the order terminating probation as written, Mr. Fraser seconded. Motion carried unanimously.

Melissa Moody, DAG presented the case regarding Michael Gardner, R.Ph. Ms. Moody and Mr. Gardner attended the meeting via teleconference. Ms. Moody addressed a typographical error regarding the date of the meeting. Ms. Moody requested the Board chair change the date from April 28 to April 23. Mr. Gardner entered the PRN program following his third arrest for DUI. Mr. Fraser motioned to suspend Mr. Gardner’s license for one year. Dr. Henggeler seconded. After discussion Mr. Fraser withdrew his motion. Mr. Fraser motioned to suspend Mr. Gardner’s license for one year, and allow appearance before the Board no earlier than six months from today’s date. Suspension would be for one year from today. Motion failed due to lack of a second. Dr. Henggeler motioned to accept the order as written with a two year suspension beginning October 13, 2009, he may appear at reasonable intervals (1 year) to request reinstatement, Mr. Fraser seconded. After discussion Dr. Henggeler withdrew her motion. Dr. de Blaquiére motioned to accept the order as written with an 18 month suspension from

today's date with Mr. Gardner having the ability to appear to request reinstatement every six months, Mr. Fraser seconded, motion carried unanimously.

Ms. Moody presented the case of James Payton, R.Ph. Mr. Payton attended the meeting via teleconference. Dr. Henggeler motioned to accept the Order as written, Mr. Fraser seconded. Motion carried with Dr. de Blaquiére abstaining.

Ms. Moody presented the case of Allen Frisk, R.Ph. Mr. Fraser motioned to reject the Order as written, Dr. Henggeler seconded. After discussion the matter is tabled until Mr. Frisk can be located by telephone.

In the matter of Yvette Flores, Pharmacy Technician Mr. Fraser motioned to accept the Order as written. Dr. de Blaquiére seconded. Motion carried unanimously.

Mr. Johnston presented the Board's travel calendar.

Mr. Frisk joined the meeting by teleconference. Mr. Fraser motioned to modify the stipulation to a two year suspension from the date the Order is signed and striking the 'automatic reinstatement' clause. Dr. Henggeler seconded, motion carried unanimously. Mr. Frisk verbally agreed to the two year suspension with the understanding he can petition the Board in one year for reinstatement.

Sonia Lee, attorney for Mr. Payton joined the meeting via teleconference for clarification of the Order and Board proceeding regarding his Order. After discussion Ms. Lee is satisfied with the Board's proceedings.

The Board revisited the Rule Book update project.

Proposed Rule #100: Pharmacist's Professional Responsibilities: Board clarifies that PAs can enter collaborative practice agreements and supports the use of the term MTM therapy. The Board decides that prescriptions cannot be depoted at a 'non-pharmacy' location for patient pickup but can be delivered to the patient anywhere. The DEA does not allow depoting of patient specific prescriptions at practitioner's offices, thus this existing language was struck.

Propose Rule #200, Student Pharmacists, and proposed rule #300, Pharmacy technicians, contain little change from existing language and are approved as written.

Proposed Rule #120, Unprofessional Conduct, and Proposed rule #600, Retail Drug Outlet Minimum Standards, are tabled until the next meeting, due to time.

During the agenda item "inspector Q&A", Mr. Collings and Mr. Brown addressed the need for a review of rule and statute concerning the DEA's rule on e-prescribing of CS, effective 6/1/10. The Board directs Mr. Johnston and Ms. Marcus to research. CRNA's

need for Controlled Substance Registrations is being addressed with the Board of Nursing.

The Board approves of Board staff delegated authority to continue processing complaints as has been done over the last 20 years and is detailed in a document provided to the Board.

The Board directs Mr. Johnston to focus efforts on pharmacist limited prescriptive authority of schedule CV substances. A discussion of counseling requirements is tabled due to time.

Mr. Johnston presents the Board's financial status and obtains approval to utilize operation funding for the capital outlay purchase of a document management program.

Mr. Fraser motioned to adjourn, Dr. Henggeler seconded. Motion carried unanimously. Meeting adjourned at 5:03 p.m.